STATE OF MICHIGAN

DEPARTMENT OF LABOR & ECONOMIC GROWTH

OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX
Petitioner **File No. 88991-001**

v

Blue Cross Blue Shield of Michigan
Respondent
_____/

Issued and entered
This 23rd day of June 2008
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On April 3, 2008, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq*. The Commissioner reviewed the material submitted and accepted the request on April 10, 2008.

Because it involved medical issues the Commissioner assigned the case to an independent review organization (IRO) which provided its analysis and recommendations to the Commissioner on April 24, 2008.

II
FACTUAL BACKGROUND

The Petitioner receives health care benefits from Blue Cross Blue Shield of Michigan (BCBSM) through the Michigan Education Special Services Association (MESSA), an underwritten group. Coverage is governed by the MESSA Choices II Group Insurance for School Employees (the certificate).

The Petitioner requested preauthorization for a total disk arthroplasty that was proposed by her doctor. BCBSM denied preauthorization of this procedure because it is considered experimental or investigational for treatment of the Petitioner's condition.

The Petitioner appealed BCBSM's denial. After a managerial-level conference on March 25, 2008, BCBSM did not change its decision and issued a final adverse determination dated March 26, 2008.

III
ISSUE

Did BCBSM properly deny preauthorization for the Petitioner's total disk arthroplasty surgery?

IV
ANALYSIS

Petitioner's Argument

BCBSM denied preauthorization for the artificial disk surgery since it is considered experimental. However, the Petitioner says other insurances such as Aetna and Cigna are covering the procedure and she does not understand why BCBSM will not.

The Petitioner says she and her doctor did not make the decision to have this surgery lightly. They took into account that the Petitioner is blind in one eye and she has already had cervical fusion at two levels just below the problem area. They felt another fusion would decrease her range of motion too much and, since she is already limited because of her vision disorder, make it impossible for her to function at work, drive, walk, or perform most daily activities.

The Petitioner asserts that the proposed procedure, the Prestige Total Disk Replacement, is approved by the FDA and has been widely used in Europe for many years. She argues that it appears safe and requires less recovery time than a fusion. The Petitioner has talked with individuals who have had this surgery and they are doing great, with marked improvement in range of motion and no pain.

The Petitioner believes that her artificial disk surgery is medically necessary and a covered benefit under her BCBSM coverage. She believes that BCBSM is required to preauthorize and pay for this surgery.

BCBSM's Argument

BCBSM believes the artificial disk replacement requested by the Petitioner is experimental or investigational and therefore not a covered benefit. It points to this exclusion in "Section 10: Exclusions and Limitations" of the certificate (page 49):

- services and supplies that are not medically necessary according to accepted standards of medical practice including any services which are considered experimental or investigational

The certificate (on page 4) defines the term "experimental or investigational" as "a service that has not been scientifically demonstrated to be as safe and effective for treatment of the patient's condition as conventional treatment." Further, BCBSM's medical policy statement for artificial intervertebral disk replacement states: "Artificial intervertebral disk replacement is experimental."

BCBSM believes that it is not required to cover the Petitioner's requested artificial intervertebral disk replacement.

Commissioner's Review

The certificate sets forth the benefits that are covered. A procedure that is not accepted as the standard of care and has not been demonstrated to be as safe or effective as conventional or standard treatment is considered to be experimental or investigational and is not a benefit under the terms of the Petitioner's coverage.

The question of whether the Petitioner's proposed artificial intervertebral disk replacement surgery is experimental or investigational for treatment of her condition was presented to an IRO for analysis as required by section 11(6) of PRIRA, MCL 550.1911(6). The IRO physician reviewer is certified by the American Board of Orthopedic Surgery; a member of the American Academy of

Orthopedic Surgery; a clinical instructor with a large university medical center; and has performed more than 100 spine surgeries. The IRO report said:

> The Prestige cervical disc was approved by the United States Food and Drug Administration (FDA) July 16, 2007. The FDA in its approval of the device has required the manufacturer to continue to track and study the device for seven (7) years total with an interim five (5) year benchmark report surveillance study to evaluate the safety and efficacy of the device. It is thus, still under investigation. The FDA literature specifically states that although artificial disc replacement has been determined to be safe, further investigation is necessary and was stipulated in the approval notification.
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> While this component has received (FDA) orthopedic and rehabilitation device panel recommendation, it still is investigational, given the lack of FDA final review and decision. According to the FDA approval letter this device is indicated for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. [The Petitioner] has an adjacent two (2) level fusion placing her outside the indications. Additionally, the surgeon states the reason for the arthroplasty is to preserve rotation. The device is designed to preserve flexion and extension, not rotation.
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> Artificial cervical disc replacement is not the standard of care in the orthopedic surgery community. Spinal fusion is the current standard of care with a 95% success rate. There are no good long term studies documenting the efficacy of this operative procedure over the traditional standard of care procedures. There are, however, studies documenting the increased risk of complications to include nerve injury and component failure.

The IRO expert concluded: "It is the determination of this reviewer that the procedure proposed, cervical disc arthroplasty, is an investigational procedure."

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation," MCL 550.1911(16) (b). The IRO reviewer's analysis is based on extensive expertise and professional judgment. The Commissioner can discern no reason why that judgment should be rejected in the present case.

Therefore, the Commissioner accepts the conclusion of the IRO that the Petitioner's proposed total disk arthroplasty surgery is investigational and finds that it is therefore not covered under the terms of the Petitioner's certificate.

V
ORDER

Respondent BCBSM's March 25, 2008, final adverse determination is upheld. BCBSM is not required to authorize or cover the Petitioner's total lumbar disk arthroplasty (artificial disk replacement surgery) since it is considered to be investigational for treatment of her condition.

Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.